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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BERKO, RETFORD O	

ART UNIT	PAPER NUMBER
1615	19

DATE MAILED: 12/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/424,247	Applicant(s) VANDERBIST ET AL.	
	Examiner Retford Berko	Art Unit 1615	

-- Th MAILING DATE of this communication appears on the cover sh et with th corr spondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) 1-13 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) 1-4 is/are rejected.

7)☐ Claim(s) 5-13 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Objections

1. Claim1, 2, 4,10, 11 and 13 are objected to because of the following informalities: cancellation of the letter "betta" from b-lactose, without initializing the cancellation. In claim 2, the word "anhydrous" in hand-written form has been inserted. No one initialed the insert or change. Appropriate correction is required.

2. Claim 5-11 and 13 are objected to under 37 CFR 1.75(c) as being in improper form because of a multiple dependent claim 4. See MPEP § 608.01(n). Accordingly, the claims 6-12 are not been further treated on the merits.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claim 1-3 are rejected under 35 U.S.C. 102 (b) as anticipated by Stevenson et al (US 4, 199, 578).

The scope of applicant's claim 1-3 is directed to a pharmaceutical excipient comprising dried (anhydrous) powder or particulate lactose with size 50-250 micrometers or 100-160 micrometers.

2. As in applicant's claims, Patent '578 teaches a pharmaceutical composition for inhalation with particle size below 400 micrometers wherein the carrier is lactose. (col 4, lin 20-60, col 5, lin 10-25 and col 6, lin 15). The disclosure in Patent '578 renders applicant's claims 1-3 anticipated under 35 U.S.C. 102(b).

3. Applicant's claim 4 is rejected under 35 U.S.C. 102 (b) as anticipated by Ganderton et al. (US 5, 254, 330).

4. As in applicant's claim 4, Patent '330 teaches a pharmaceutical excipient in dry powder form for inhalers wherein the excipient is crystalline lactose (abstract; col 6, lin 25 and col 4, lin 60) with particle size of 60-90 micrometers (col 5, lin 10, col 8, lin1) and rugosity greater than 2.0 (col 1, lin 40-65). The disclosures in Patent '330 render applicant's claim 4 anticipated under 35 U.S.C 102(b).

5. A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Calims 1-3 are rejected under 35 U.S.C. 102(a) as anticipated by Baichwal et al (US 6, 612, 053).

As indicated above, applicant claims anhydrous or dry powder, i.e. particulate lactose as excipient in a pharmaceutical formulation. Patent '053 teaches particle-based pharmaceutical formulation for delivering medication through insufflation comprising of lactose with particle size of 45-355 microns or 63-125 microns (col 17, lin 5; col 7, lin 45-65; col 8, lin 50-65; col 18, lin 20 and col 15, lin 10-20). The disclosures in Patent '053 renders applicant's claims 1-3 anticipated under 35 U.S.C. 102(a).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ganderton et al (US 5, 254, 330) in view of Ganderston (US5, 376, 386).

8. In claim 4, applicant is claiming that the invention is a pharmaceutical excipient, in powder form, that is anhydrous lactose with particle size of 50-250 micrometers, 100-160 micrometers and rugosity between 1.9 and 2.4.

9. Patent '330 teach a pharmaceutical excipient in powder form, particle size of 5-1000 micrometers that is lactose with rugosity equal to 1.75 (col 6, lin 25 to 60 and col 8, lin 1). Patent '330 does not specifically teach that the rugosity of the excipients is between 1.9 and 2.4, although Patent '330 alludes the the fact that the rugosity of conventional excipients measured by air permeametry has been found to be at least 1.96 and generally greater than 2.0 (col 1, lin 50-65).

10. Patent '386 teaches that the particle size of the lactose used as excipint in inhaler formulation was 60-90 micrometers (col 5, lin 30). Patent '386 also teaches that the rugosity of conventional excipients is at least 1.96 and generally greater than 2.0 and that the redistribution of drug particles from compositions comprising carriers is facilitated if the rugosity of the carrier particles is reduced (col 1, lin 60-65).

11. One of ordinary skill in the art would have been motivated to use lactose as excipients in a pharmaceutical formulation with particle size from 5-1000 micrometers and reduce the rugosity beginning from a figure which is greater than 2 to a figure between 1.9 and 2.4. One of ordinary skill would have expected to obtain a carrier with the particle size and rugosity that is reduced enough to provide a composition that does not destabilize the pharmaceutically active materials with which it is formulated.

12. Claim 4 is rejected under 35 U.S.C. 103 (a) as unpatentable over Ganderton et al (Patent '330) in view of Ganderton (Patent '386).

Correspondence

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Retford Berko whose telephone number is 703-305-4442. The examiner can normally be reached on M-F at 8:00 a.m.-5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-9903 for regular communications and 703-746-9903 for After Final communications.

An inquiry of a general nature or relating to the status of this communication or proceeding should be directed to the receptionist whose telephone number is 703-308-1243.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600